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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/621,116 | 07/16/2003 | John C. Smith | 06275-276002 / LDG/Z70675 | 9087 |

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| EXAMINER | |
|---|---|
| SWITZER, JULIET CAROLINE | |
| **ART UNIT** | **PAPER NUMBER** |
| 1634 | |

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/621,116 | SMITH, JOHN C. | |
| | Examiner | Art Unit | |
| | Juliet C. Switzer | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 3, 4, 5, 6, 7, and 20 drawn to a method for the diagnosis of a polymorphism using nucleic acid analysis and diagnosis of a disease, classified in class 435, subclass 6

II. Claims 1, 2, 3, 4, 5, 13, and 20 drawn to a method for the diagnosis of a polymorphism using nucleic acid analysis, and treatment of a disease class 424, subclass 94.1.

III. Claims 8, 9, 10, 11, 12, and 16, drawn to isolated nucleic acids, classified in class 536.

IV. Claims 14 and 15, drawn to a method to prepare a medicament and a pharmaceutical pack, classified in class 424, for example.

V. Claims 17 and 18 drawn to computer readable media, classified in class 707, subclass 100.

VI. Claims 19, drawn to a method of performing sequence identification using a step of comparison to a sequence on computer readable media, classified in class 702, subclass 20.

### *Further Restriction Requirement Applicable to All Groups*

Each group detailed above reads on more than one patentably distinct group, wherein each of the distinct group is drawn to methods for the detection of separate polymorphisms,

nucleic acids comprising different polymorphic variants, treatment of a patient after diagnosis using more than one polymorphism, etc. For example, group I above encompasses a multitude of different inventions, that is, methods for detecting each of the "one or more of" each of the nine different recited nucleic acid polymorphisms. For the elected group (of groups I-VI), applicants must further elect single combination of "one or more" polymorphisms for examination in the appropriate product or method claim. For example, if applicant elects group I, applicant should further elect one combination of the nucleotide polymorphisms for examination. Upon allowance of the claims with regard to elected combination, any claims that recite larger groupings that include the elected combination will be rejoined.

If applicant elects group III, applicant should elect sequences which comprise a single polymorphism, and identify the sequences (by SEQ ID NO) that are related to the elected invention.

It is noted that claims 1-5 are included in both groups I and II. Claims 1-5 will be examined with whichever group is elected.

Each polymorphic sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differ in structure and in function and in biological activity. Further, even where the nucleic acid changes have no effect on protein structure or function, these sequences themselves represent allelic variations which have different diagnostic and therapeutic implications.

Prior to allowance, non-elected subject matter will be required to be deleted from any allowable claims.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and III and inventions II and III and inventions V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of inventions III can each be used in separate methods from those instantly disclosed. The nucleic acids of invention III can be used in other methods, such as to express the encoded polypeptide, for nucleic acid purification assays and for aptamer assays. In the case of inventions V and VI, the products of invention V can be used in a variety of methods, such as for homology searching for identifying newly discovered nucleic acid sequences, or the storing of additional sequence data.

3. Inventions I and II and inventions I and IV and inventions I and VI and inventions II and IV inventions II and VI and inventions IV and VI are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods with different goals, distinct method steps and requiring different reagents and different techniques. The methods of invention I are drawn to the detection of nucleic acid polymorphisms and diagnosing of diseases, and require the use of nucleic acid analysis techniques, such a DNA sequencing or nucleic acid hybridization assays for the goal of the diagnosis of disease. The methods of group II, while

encompassing some of the same method steps as the methods of group I require different process steps involved in the treatment of disease. The methods of group IV are directed towards the preparation of medicaments and would require the steps and reagents necessary to prepare the IV is not disclosed for use in the methods for diagnosing polymorphisms and diseases of group I. The methods of group VI differ from all of these because they involve the "in silico" identification of nucleic acid sequences by comparing data on a computer readable media (i.e. disk) for sequence identification. The methods of group VI do not recite or require analysis of nucleic acids themselves, but the analysis of data. Likewise, the methods preparing a medicament of group IV are not related to the methods of data analysis of group VI because these do not have common goals, process steps or outcomes.

4. Inventions III and V are unrelated to group IV. Inventions I and V, inventions II and V, and inventions III and VI are also unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Each of the groupings represents unrelated inventions because these are not disclosed for use in the particular methods provided. Neither the nucleic acids of group III nor the computer readable media of group IV are disclosed for use in the methods for preparing medicaments of group IV. Likewise, the method of group I and II do not recite or require the use of the computer readable media of invention V. The methods of group VI do nor recite or require the use of the nucleic acids molecules of invention III.

5. The products of groups III, IV, and V are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acids of Group III are

composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The medicament of group IV is a chemical compound designed to have bioaffecting activity for the treatment of disease. The computer readable media of group V is a comprised of, for example, a computer disk or some other computer memory. Furthermore, the products of Groups III and IV can be used in materially different processes, for example, the DNA of Group III can be used in hybridization assays. The pharmaceutical pack can be used to treat disease or conditions associated with the FLT-1 gene. The media of group V is used in a computer to transmit tata. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups III, IV, and V are patentably distinct from each other.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-VI, as well as the examination of each individual polymorphism, require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday, Tuesday, or Thursday, from 9:00 AM until 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached by calling (571) 272-0735.

The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of

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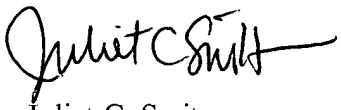

Juliet C. Switzer
Primary Examiner
Art Unit 1634

February 28, 2006